DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

JAN 26 2006

Allesee Orthodontic Appliances, Incorporated
C/O Ms. Colleen Boswell
Director, Corporate Compliance
Sybron Dental Specialties, Incorporated
1717 West Collins Avenue
Orange, California 92867

Re: K040874
Trade/Device Name: Red, White, & Blue
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: II
Product Code: NXC
Dated: March 31, 2004
Received: April 02, 2004

Dear Ms. Boswell:

This letter corrects our substantially equivalent letter of June 18, 2004.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent, for the indications for use stated in the enclosure, to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Chiu S. Lin, PhD
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (If known): K040874

Device Name: *Red, White & Blue*

Indications For Use:

Red, White & Blue is a series of three, clear, lightweight, plastic retainers intended to be used to correct minor to intermediate anterior tooth mal-alignments in patients with permanent dentition (second molars) by moving teeth progressively to a final, treated state.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K040874

K040874

JUN 18 2004

SYBRON DENTAL SPECIALTIES

Section III - 510(k) Summary of Safety and Effectiveness

Submitter:

Allesee Orthodontic Appliances, Inc.
13931 Spring Street
Sturtevant, WI 53177

Contact:

Colleen Boswell
Sybron Dental Specialties, Inc.
(714) 516-7484 - Phone
(714) 516-7488 - Facsimile

Date Summary Prepared: June 2004

Device Name:

- Trade Name – *Red, White & Blue*
- Common Name – Preformed Tooth Positioner
- Classification Name -- Preformed Tooth Positioner, per 21 CFR § 872.5525

Devices for Which Substantial Equivalence is Claimed:

- Align Technology, *Invisalign*

Device Description:

Red, White & Blue is a retainer system which offers a solution to those patients who want a simple, aesthetic system to correct minor to intermediate tooth mal-alignments without the use of conventional wire and bracket orthodontic technology. The system consists of a series of three, clear lightweight, plastic retainers. Each appliance applies incremental tooth correction by means of repositioning the anterior teeth. In this way, the patient's teeth will get progressively closer to the desired final state.

The dental practitioner will make dental impressions of his patient's teeth and select the anterior teeth that are to be repositioned. The impressions or a model of the teeth made from the impression is then sent to AOA along with a prescription form. The teeth selected for treatment are cut from the model and progressively repositioned. After each repositioning, AOA will create a corresponding appliance for a total of three active appliances. Depending upon the complexity of the case, it is possible that a patient may require less or more than the series of three appliances. *The Red, White & Blue* retainers are mailed to the dental

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practitioner, who in turn, will provide them to their patient with the instructions for use.

Intended Use of the Device:

The intended use of *Red, White & Blue* is to correct minor to intermediate anterior tooth mal-alignments in patients with permanent dentition (second molars) by moving teeth progressively through the use of three, clear, lightweight, plastic retainers.

Substantial Equivalence:

Red, White & Blue is substantially equivalent to other legally marketed devices in the United States. *Red, White & Blue* is used in a manner similar to the *Invisalign* system marketed by Align Technology.